UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE LORAZEPAM & CLORAZEPATE ANTITRUST LITIGATION	**MDL Docket No. 1290** **Misc. No. 99ms276**
This Order applies to: **All Actions**	

ORDER

It is hereby

ORDERED that the attached letter received by the Court on June 14, 2001, which objects to the settlement proposed in this case, shall be filed by the Clerk of the Court. It is further

ORDERED that in addition to sending all counsel of record copies of this Order and the attached letter, a copy of this Order and the attached letter shall be forwarded to the claims administrator at the following address:

Lorazepam/Clorazepate Settlement Administrator
P.O. Box 1605
Faribault, MN 55021-1605

June 28, 2001

Thomas F. Hogan
United States District Judge

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1209 Landmark Two
1920 Frontage Road
Cherry Hill N.J. 08034
June 11, 2001

The Honorable Thomas F. Hogan
Court For The District of Columbia
Washington D.C.

Your Honor:

I am writing this letter in opposition to the proposed settlement between the F.T.C. and Mylan Labs. After reading the proposed settlement agreement, it is my understanding the purpose is to re-imburse for the overcharge that we the consumer paid. The time frame specified in the agreement is Jan 1, 1998 thru Dec 31, 1999. After march 6, 1998 Mylan who controlled the price, increased my cost from 100 1mg Lorazepam at $9.99 - my next purchase was $58.99. So including Jan & Feb of 1998 is bogus. They did not increase the price at that time. The price today for the same amount of this medication, depending on the pharmacy is $39.95 to $54.95.

This illustrates to me that Mylan Labs because of their illegal monopolistic actions did two things. They got the price up, and managed to have the very

PEOPLE AFFECTED, PAY THE FINE INDIRECTLY THRU THE PRICE INCREASE. FURTHUR MORE MYLAN LABS ADMITS NO GUILT, THE F.T.C. ACCEPTS THIS PLEA AND THE PUBLIC BE DAMNED. I WAS UNDER THE IMPRESSION THE PURPOSE OF THE FEDERAL TRADE COMMISSION WAS TO PROTECT THE PUBLIC FROM ILLEGAL, MONOPOLISTIC PRACTICES BY BUSINESSES. MY PERCEPTION IS THAT MYLAN LABS & THE CO-CONSPIRATORS WERE THE ONES PROTECTED, NOT THE PUBLIC. WHAT IS MORE OUTRAGEOUS IS THAT THIS ACTION OPENS THE DOOR FOR OTHER BUSINESSES TO DO THE SAME, IF THIS SETTLEMENT IS APPROVED. I AM SURE WE WILL FIND OTHER BUSINESSES DOING THE SAME. I STRONGLY DISAPPROVE OF THIS PROPOSED SETTLEMENT.

RESPECTFULLY

HERBERT GOLDMAN

P.S. I HAVE ENCLOSED AN ARTICLE FROM CONSUMERS REPORTS JULY 2001 - THIS ILLUSTRATES MY OBJECTION. YOUR COURT CAN RECTIFY THIS. MISCARRIAGE OF JUSTICE.

GENERIC DRUGS

The stalling game

Sweetheart deals and patent extensions keep lower-cost generic drugs from consumers.

If you or a family member have taken brand-name prescription drugs for such ailments as allergies, anxiety, heartburn, or high blood pressure, you can stop wondering why your bills have been so high. In many cases, cheaper generic equivalents have not made it to the marketplace as early as they could have after expiration of the typical 20-year drug patent.

Our interviews with consumers, federal regulators, and drug manufacturers and their trade groups, and our review of recent Federal Trade Commission (FTC) actions, paint a picture of a pharmaceutical industry busily engaged in stalling the entry of generic drugs to the marketplace. In April, the FTC filed the third complaint in a year charging drug makers with anticompetitive practices (see "Sweetheart Deals," below).

The Bush administration recently gave the FTC a green light to begin an industry-wide investigation; the FTC has issued subpoenas to 100 pharmaceutical companies—brand-name and generic manufacturers alike. Investigators will focus on the business relationships between brand-name and generic-drug manufacturers, says outgoing FTC chairman Robert Pitofsky.

Consumers are bearing the financial brunt of tactics that delay the introduction of generic drugs, which typically cost 25 to 50 percent less than their brand-name equivalents. Consider David Hyams, 75, of Corte Madera, Calif., who began taking *Hytrin* (terazosin) to control his high blood pressure in 1992. With no drug insurance, Hyams paid the then $1-a-day cost of the brand-name drug himself. And the price kept going up. By 1999 it was up to $1.50 a day. In August of that year, a generic terazosin finally became available. "Of course, I made the switch," says Hyams.

As more generic versions of the drug entered the market, prices were driven down. By spring 2001, Hyams was paying just 40 cents a day for his dose of the drug. But if it weren't for a sweetheart deal, one of several tactics used to stall competition, generic versions of *Hytrin* could—and should—have been available months earlier, according to the FTC.

It's a high-stakes game for drug manufacturers, their shareholders, and the public. Maintaining a monopoly on a product by delaying a generic introduction by even a day can mean millions in profits for the brand-name company. And the stakes will soon get higher. Patents on 21 best-selling drugs with annual U.S. sales approaching $20 billion will expire over the next five years.

"Brand-name pharmaceutical companies are using every possible tactic—legal or illegal—to rob Americans of billions of dollars over the next few years by delaying for as long as possible the entrance of generics to market," says Sidney Wolfe, M.D., of the nonprofit Public Citizen Health Research Group, a Washington watchdog group. "It's an economic and a health scandal. It prevents people who can't afford the brand-name version—but might be able to afford the generic version—from getting the drugs they need."

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, was designed to foster generic competition by

PHOTOGRAPH BY STEPHEN WEBSTER

striking a balance between the interests of generic and brand-name companies. The legislation made it cheaper and easier for generic makers to win FDA approval for their drug. It gave some generic companies a six-month head start on the competition. And it rewarded makers of brand-name drugs with additional years of effectiv patent life to make up for market time los awaiting FDA approval. True innovator who market first-of-their-kind drugs get up to five additional years of patent protection

In recent years, companies have gone al out to evade the spirit of the 1984 law. They've been accused of the following:

Legislative stealth. Sneaking patent-extending riders into complex and unrelated legislative packages.

Disabling competitors. Paying chemical supply houses not to sell needed ingredients to rival drug manufacturers.

Sweetheart deals. Paying competitors to stay out of the market.

Unreasonable delays. Filing unfounded "citizen petitions" and patents to delay the marketing of a generic drug.

There are times when delay may be justified: Market exclusivity is sometimes granted to encourage research in neglected areas. Since 1998, the Department of Health and Human Services has given makers of more than two dozen brand-name drugs an extra six months of market exclusivity as an incentive to conduct clinical trials to determine how well their medicines work in children. Supporters of the program say it rewards drug manufacturers for performing time-consuming and crucial research. Critics charge that this is a government subsidy program that pays manufacturers for research they should be obligated to undertake.

LEGISLATIVE STEALTH

Most market monopolies benefit only drug companies and their stockholders. That's why drug manufacturers have lobbied congressional representatives to insert special patent-extending clauses for a particular drug into must-pass appropriation legislation. In 1996 a clause extending for two years the G.D. Searle patent on its nonsteroidal anti-inflammatory drug *Daypro* (oxaprozin) passed as part of the omnibus budget bill, the legislation that prevented a federal government shutdown.

Since then, however, Congress seems to be more alert. It cut out the rider for a patent extension on Hoffmann-La Roche's pain reliever *Toradol* (ketorolac) that was inserted in the 1997 emergency legislation for flood victims and military missions. And last year Sen. Edward M. Kennedy, D-Mass., and other senators held a press conference to expose an attempt to extend Schering-Plough's patent for the allergy drug *Claritin* (loratadine) in the 2001 Military Construction Ap[illegible]

DISABLING OTHER MANUFACTURERS

It's not only brand-name companies that try to dodge competition. A major generic company has been charged with going to great lengths to remain the only player in its category. Mylan Laboratories, the nation's second largest generic-drug manufacturer, has settled FTC charges that it conspired with three chemical suppliers to deprive other generic-drug makers of the ingredients necessary to manufacture two generic antianxiety drugs, clorazepate and lorazepam. With the competition disabled, Mylan raised the wholesale price of clorazepate from $11.36 to $377 for a 500-count bottle of 7.5-milligram (mg) tablets in January 1998, says the FTC. Two months later Mylan raised the wholesale price of lorazepam from $7.30 to $190 for a 500-count bottle of 1-mg tablets. The arrangement cost consumers more than $120 million, the commission says.

In the largest monetary settlement in FTC history, Mylan Laboratories, denying wrongdoing, has agreed to pay $147 million to compensate patients, insurers, managed-care organizations, and state agencies and to pay attorneys' fees. Affected consumers can call 800 899-5806 or find information at *www.agsettlement.com*.

SWEETHEART DEALS

In March 1998 generic manufacturer Geneva Pharmaceuticals received FDA approval to be the first to market generic capsules of *Hytrin*, used for benign prostate enlargement and high blood pressure. Then Geneva told Abbott Laboratories, which developed the drug, it would launch a generic version of *Hytrin* unless Abbott paid to keep

Growing confidence in generic drugs

To win FDA approval, a generic-drug maker must show that its product contains the identical active ingredients as its brand-name counterpart. And it must prove that the generic is bioequivalent, usually by showing that the active ingredient enters and leaves the bloodstream as rapidly and completely as its branded twin. Drugs that do should have the same therapeutic effect.

A recent FDA review of the bioequivalence of the 273 generic drugs approved in 1997 found just a 3.5 percent difference, on average, between generic and branded drugs. That's no greater than the difference between one batch of a brand-name drug and another batch off the same assembly line. "Based on these results, practitioners and the public may be assured that if the FDA declares a generic drug to be therapeutically equivalent to an innovator drug, the two products will provide the same intended clinical effect," Jane Henney, M.D., then FDA commissioner, wrote in the December 1999 issue of the Journal of the American Medical Association.

That assurance even applies to 25 medications—primarily for epilepsy, heart-rhythm disturbances, and pulmonary disease—that are effective only within a very narrow range of blood levels and so have been dubbed "Narrow Therapeutic Index," or NTI drugs, says Gary Buehler, acting director of FDA's Office of Generic Drugs. He says a growing body of research supports the FDA's view that patients on NTI drugs can switch to generics without special monitoring. The exception is the thyroid hormone levothyroxine *(Euthyroid, Levoxyl, Levothroid, Synthroid)*; bioequivalency data are still lacking, so Consumers Union's medical consultants advise patients not to switch products without being monitored.

The FDA has grown so confident of the generics it approves that it has stopped its longtime practice of designating them and their branded counterparts "B" drugs if they're not interchangeable because of actual or potential bioequivalence problems. "That was an artifact of the past," Buehler says. "We no longer approve drugs that are not equivalent."

Nevertheless, about 65 drugs approved in the past are still "B-rated," including particular dosage forms of common medications such as albuterol for asthma, estradiol for hormone-replacement therapy, and prednisone for inflammatory disease. Patients on "B" drugs who switch from brand to generic (or between generics) should be monitored. For more information on "B-rated" medications, refer to the "orange" book, the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations," which can be found at *www.fda.gov/cder/orange/default.htm*.